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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,951	02/05/2006	Maisam Mitalipova	18377-0061	8860

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EXAMINER
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HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
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1649

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/539,951	<b>Applicant(s)</b> MITALIPOVA ET AL.	
	<b>Examiner</b> Robert C. Hayes, Ph.D.	<b>Art Unit</b> 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 1-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/25/05; 2/17/06</u>  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group V (claims 46-55) in the reply filed on 5/01/08 is acknowledged. The traversal is on the ground(s) that “the five (5) groups of claims relate to a single *general* inventive concept because they share a corresponding *special* technical feature”. This is not found persuasive because a “special” technical feature does not exist, by definition, if it is a “general inventive concept”, or if it does not make a contribution over the prior art (i.e., as it relates to claim 1). In contrast, Applicants’ argument that “the common technical feature shared by each group is the use of MEDII conditioned medium” makes little sense, unless Applicants intent is to claim MEDII conditioned medium as their invention, and then argue that this is their contribution over the prior art in accordance with PCT Rule 13.2. As previously made of record, PCT Rule 13 does not provide for multiple products or methods in a single application. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5/01/08.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 46-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite or incomplete for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

First, because compositions must consist of at least two components, the composition claims of claims 46-55 are incomplete.

Second, the term "essentially" in claim 54 is a relative term which renders the claim indefinite. The term "essentially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In other words, it is unclear when medium is "essentially" serum-free, versus at what point medium is no longer "essentially" serum-free.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 46-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Carpenter (1999, US Patent 5,968,829; IDS Ref #8).

Carpenter teach compositions comprising "nestin"-positive neural stem/progenitor cells in serum-free DMEM/F-12 medium comprising the low molecular weight component, insulin (which comprises proline), and the neural inducing factors, EGF, bFGF, PDGF, NGF & LIF, which were also proliferated up to 130 cell divisions and 90 days in culture (e.g., cols. 2-4 & 8-9,

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Figs. 2B & 3; as it relates to claims 46, 47-50, 52 & 54). In that the MEDII medium is defined in claim 55 to only consist of at least one of the components (a)-(f), the limitations for being stabilized by MEDII medium (i.e., a process) throughout the claims is also met.

The issue then becomes that if the product in a product-by-process claim (i.e., a “composition *comprising* an isolated neural cell”, which is then stabilized or made by any process that results in a product that is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process (i.e., as it also relates to claim 51). *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983). In addition, because the claim language for a “composition” merely requires “an isolated neural cell, wherein the cell expresses nestin” and does not require MEDII medium, itself, as a component within the composition (which is further ill-defined in the claims), claim 53 is further anticipated because HepG2 conditioned medium is not claimed as part of the composition, and therefore, is only a process that carries no patentable weight for the claimed product.

4. Claims 46-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Bresagen Limited/ Rathjen et al (WO 01/51611; IDS Ref #14).

Rathjen et al teach compositions comprising “nestin”-positive neuroectoderm / EPL embryoid bodies/ neural stem/progenitor cells in serum-free HepG2- conditioned MEDII medium (e.g., pgs. 7, 9, 11, 14, 28, 33, 37 & 47; as it relates to claims 46 & 52-55), in which WO99/53021 (IDS Ref #18) is incorporated by reference in ‘611 and states that “EPL cell morphology could be maintained with extended culture of greater than 40 passages, or 100 days

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(data not shown)” (pg. 46 of ‘021). Thus, the process limitations of claims 47-50 are also anticipated. In that contact with MEDII does not reasonably change the nestin positive neural cells of Rathjen even after “one year”, the limitations of claim 51 are further anticipated. Note that if the product in a product-by-process claim (i.e., a “composition *comprising* an isolated neural cell”, which is then stabilized or made by any process that results in a product that is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process (i.e., as it relates to claim 51). *In re Thorpe.*, 227 USPQ 964, 966 (Fed. Cir. 1985); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983).

### ***Conclusion***

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Stucker, can be reached on (571) 272-0911. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert C. Hayes, Ph.D./  
Primary Examiner, Art Unit 1649  
July 8, 2008